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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/677,444	10/02/2003	Kevin A. Mansmann	KM-GEL-2	9002

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EXAMINER	
MILLER, CHERYL L	

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 11/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	**Application No.** 10/677,444	**Applicant(s)** MANSMANN, KEVIN A.	
	Examiner Cheryl Miller	**Art Unit** 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23 and 25-27* is/are rejected.

7)☒ Claim(s) *24* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments filed September 11, 2006 have been fully considered but they are not persuasive.

The applicant has argued that Stoy's (US 6,264,695) implant is not for use in a synovial joint. The examiner's position is that an implant *for replacing* damaged cartilage in a joint lubricated by synovial fluid, is intended use language. Stoy's implant is capable (sized and configured) of being placed in a synovial joint, thus still reads on the claims. The applicant has also argued that Stoy's implant is not anchored to bone. The examiner disagrees. First, claim 8 only requires an implant sized and designed *for* anchoring. An anchor has not been positively claimed, all that is required is that the implant be adapted to be able to be anchored, for example, *capable of being* sutured or nailed to the bone. Sutures and nails however need not be present. Further, it is the examiners position that a friction fit or compression between two bones may be considered to be anchored in place. Sutures, staples etc are not claimed and are not required.

The applicant has argued that McAuslan's chemical treatment produces etching making a non smooth surface. The examiner's position is that the same type of chemical treatment used by McAuslan is used by the applicant, treatment with an acid such as sulfuric acid. Since the same method of surface treatment is conducted, inherently the same amount of smoothness exists on the hydrogel surface.

The applicant has argued that Stoy (US 6,264,695) in view of Stoy (US 2004/0070107) does not disclose how an anchor and how the anchor would function effectively. The examiner disagrees. The examiner's position is that an implant *for replacing* damaged cartilage in a joint lubricated by synovial fluid, is intended use language. Stoy's implant is capable (sized and configured) of being placed in a synovial joint, thus still reads on the claims. The applicant has also argued that Stoy's implant is not anchored to bone. The examiner disagrees. First, claim 8 only requires an implant sized and designed *for* anchoring. An anchor has not been positively claimed, all that is required is that the implant be adapted to be able to be anchored, for example, *capable of being* sutured or nailed to the bone. Sutures and nails however need not be present. Further, it is the examiners position that a friction fit or compression between two bones may be considered to be anchored in place. Sutures, staples etc are not claimed and are not required.

The applicant has argued that Oka (US 5,314,478) does not disclose a flexible fiber matrix, but instead metal or ceramic. It is the examiner's position that "flexible" has not been claimed and is not an inherent feature of fibrous. The fibrous matrix of Oka is still believed to read on the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3-8 and 11-12 are rejected under 35 U.S.C. 102(e) as being anticipated by Stoy (US 6,264,695 B1). Stoy discloses an implant (fig.17A-18) comprising a hydrogel (including PAN, col.6, lines 54-58; col.8, lines 17-23) having at least one smooth and lubricious surface (entire outer surface is smooth) having a negative charge (col.7, lines 42-44; col.10, lines 3-10; col.19, lines 17-19), and a fibrous matrix (the fibrous matrix may be considered either 1.fibular hydrogel mesh component, col.9, lines 10-20; or 2.fiber reinforcement, seen in figs.17-18, col.13, lines 39-55) extending through at least a portion of the hydrogel (fibers seen in figs are completely embedded, and fibular matrix component extends throughout entire hydrogel), providing reinforcement.

Referring to claims 3-6, Stoy discloses the lubricious surface to contain the claimed atoms, groups (col.10, lines 3-10; col.14, lines 1-2, it is also noted some of the groups listed are inherently present, since Stoy discloses use of the same materials as the applicant).

Referring to claim 7, Stoy discloses the entire outer surface to be smooth and lubricious, therefore capable of articulating. Stoy discloses the use of the implant with articular hyaline cartilage (col.14, lines 6-7).

Referring to claim 8, Stoy discloses an implant *designed for* anchoring to bone (the implant is for use inbetween two vertebral bones and capable of being anchored, by friction fit between two bones).

Referring to claims 11-12, Stoy discloses use of the claimed hydrogel materials (col.8, lines 31-67; col.9, lines 1-60).

Claims 1, 8-9, 19, and 25-26 are rejected under 35 U.S.C. 102(b) as being anticipated by McAuslan (US 4,836,884). McAuslan discloses an implant (col.1, lines 5-7) comprising a hydrogel (hydrogel layer, col.2, lines 65-68) having at least one smooth and lubricious surface (hydrogel surface; col.2, lines 35-43) having a negative charge (col.2, lines 35-42, 50-59; col.7, lines 35-42), and a fibrous matrix (substrate; col.3, lines 3-9) extending through at least a portion of the hydrogel (hydrogel coats the top of the substrate, so will penetrate some of the substrate inherently), providing reinforcement.

Referring to claims 8-9, 19, and 26, McAuslan discloses the substrate (col.3, lines 3-9; Dacron for instance a porous fabric) to only be coated on one side, therefore the other side inherently remains uncoated and thus retains it's porous structure, therefore capable of anchoring and ingrowth.

Referring to claim 25, McAuslan discloses a method of making an implant comprising chemically treating the above implant in order to impart a negative charge (col.3, lines 10-19; col.5, lines 40-45; col.6, lines 63-65; col.7, lines 29-69).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stoy (US 6,264,695). Stoy discloses an implant having a smooth and lubricious hydrogel surface with a negative charge (col.7, lines 42-44; col.10, lines 3-10; col.19, lines 17-19), however does not disclose any specific charge densities. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the charge density claimed (-100 to -250 mmolar), since once the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Claims 9, 13-23, and 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stoy (US 6,264,695) in view of Stoy (US 2004/0070107 A1). Referring to claim 25, Stoy 695' discloses a method of making an implant for replacing cartilage (col.14, lines 4-8) comprising creating a synthetic hydrogel (including PAN, col.6, lines 54-58; col.8, lines 17-23) having a smooth and lubricious surface and a fibrous reinforcing matrix (the fibrous matrix may be considered either 1.fibular hydrogel mesh component, col.9, lines 10-20; or 2.fiber reinforcement, seen in figs.17-18, col.13, lines 39-55) extending through a portion of the hydrogel. Stoy 695' discloses the hydrogel surface to have a negative charge (col.7, lines 42-44; col.10, lines 3-10; col.19, lines 17-19), however does not disclose *how* the negative charge is imparted on the surface. Stoy 107' teaches in the same field of hydrogel implants, a process of chemically treating a hydrogel surface, using sulfuric acid (P0048; P0027; the same hydrogel, PAN disclosed by Stoy 695'), to impart a negative charge on the surface, providing the implant with a more lubricious surface for articulating joints (P0048). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Stoy 695's hydrogel implant having a negative charge however silent to the method of imparting the charge, with Stoy 107's teaching of a method of imparting a negative charge on hydrogel implants, in order to provide a method of receiving the result of Stoy 695'.

Referring to claims 9, 13, 19, and 26, Stoy 695' discloses a hydrogel implant for a human joint, however does not disclose an anchoring surface for ingrowth on the implant. Stoy 107' teaches in the same field of hydrogel joint implants, providing a hydrogel of the same material used by Stoy 695', with a porous surface, for providing attachment and anchorage (P0049; P0050; P0051). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Stoy 695's hydrogel joint implant, with Stoy 107's teaching of imparting porosity on a hydrogel surface to provide a joint implant with an anchoring surface.

Referring to claims 14 and 20, Stoy 695' discloses an implant having a smooth and lubricious hydrogel surface with a negative charge (col.7, lines 42-44; col.10, lines 3-10; col.19, lines 17-19), however does not disclose any specific charge densities. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the charge density claimed (-100 to -250 mmolar) since once the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Referring to claims 15-18 and 21-23, Stoy 695' discloses the lubricious surface to contain the claimed atoms, groups (col.10, lines 3-10; col.14, lines 1-2, it is also noted some of the groups listed are inherently present, since Stoy discloses use of the same materials as the applicant). Stoy discloses the entire outer surface to be smooth and lubricious, therefore capable of articulating. Stoy discloses the use of the implant with articular cartilage (col.14, lines 6-7). Stoy discloses use of the claimed hydrogel materials (col.8, lines 31-67; col.9, lines 1-60).

Claims 1, 8-10, and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oka et al. (US 5,314,478) in view of Stoy (US 2004/0070107A1). Referring to claims 1 and 25, Oka discloses an articulating joint implant (col.1, lines 5-10; C; fig.1) and method of making the implant comprising providing a synthetic hydrogel (g) having a smooth and lubricious surface (col.3, lines 30-34, 65-68; col.4, lines 27-33), and a fibrous matrix (c1) extending at least partially through the hydrogel, reinforcing the gel. Although Oka discloses the implant to have a smooth and lubricious hydrogel surface, Oka does not disclose the surface to have a negative charge. Stoy teaches in the same field of articulating joint implants (fig.2, 3), a method of chemically treating the hydrogel surface in order to provide a smoother surface for articulation (P0048). It would have been obvious to one having ordinary skill in the art to combine Oka's hydrogel joint implant, with Stoy's teaching of treating hydrogel surfaces of joint implants, in order to provide a surface with a negative charge, better adapted for articulation.

Referring to claims 8-10 and 26-27, Oka discloses a porous anchoring surface (titanium mesh, c1; fig.1), and a non-planar interface layer (a non-planar cross-section of the anchor surface may define an "interface" layer that is non-planar, and since it is a mesh, it has perforations) having perforations.

Allowable Subject Matter

Claim 24 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (571) 272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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